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**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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*Ex parte* FRANCISCO JAVIER GARCIA-LADONA

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Appeal 2007-4456
Application 09/869,814
Technology Center 1600

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Decided: January 3, 2008

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Before ERIC GRIMES, NANCY J. LINCK, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of treating cerebrovascular disorders such as migraine using a 5-HT5 receptor binding partner, which the Examiner has rejected as lacking an adequate description in the Specification. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

## BACKGROUND

"At least seven different receptor classes mediate the manifold physiological activities which are ascribed to an involvement of the neurotransmitter serotonin" (Specification 1). The Specification discloses that "they are designated by 5-HT1, 5-HT2, 5-HT3, 5-HT4, 5-HT5, 5-HT6 and 5-HT7" (Specification 1). According to the Specification, "the 5-HT1 class includes receptors which can be divided into at least five subclasses, which are designated by 5-HT1A, 5-HT1B, 5-HT1C, 5-HT1D and 5-HT1E" (Specification 1).

The Specification teaches that until "now, compounds having selective affinity for 5-HT1 receptors have been considered for the treatment of migraine" (Specification 3).

Appellant teaches that the "present invention therefore relates to selective binding partners for 5-HT5 receptors, whose binding affinity for 5-HT5 receptors is greater than for one or more 5-HT receptors other than 5-HT5" (Specification 3).

## STATEMENT OF THE CASE

*The Claims*

Claims 29-32 and 34-36 are on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claim 29, which is representative and reads as follows:

> 29. A method for treating migrainous cerebrovascular disorders which comprises administering to a subject in need thereof an effective amount of at least one binding partner for a 5-HT5-receptor whose binding affinity for the 5-HT5-receptor is at least 10 times greater than its binding affinity for a 5-HT1D-receptor.

*The Issues*

Claims 29-32 and 34-36 stand rejected under 35 U.S.C. § 112, first paragraph, on the basis that the claims are drawn to methods of treating migraine which use compounds that bind to the 5-HT-5 receptor. According to the Examiner,

> the present specification does not disclose the structure or physical properties of any compounds encompassed by the claims, and required to practice the claimed methods, and . . . the structure of such compounds cannot be deduced from any known structure-function correlation, even considering the knowledge of one skilled in the art.

(Answer 5.) Further, Appellant did not provide a written description in the Specification of any compounds meeting the claim limitations (*see* Answer 3). A single compound, HK02-01, whose structure is not provided, is disclosed in the Garcia-Ladona declaration (*see* Answer 3). The Examiner finds that the Specification does not provide an adequate written description of the claimed method (Answer 5).

We agree with the Examiner that the Specification does not adequately describe the claimed method. Describing a claim to a method requires describing the compounds used in the method.

> [T]he inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods. As the district court observed, "[t]he claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment."

*University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed. Cir. 2004).

Claim 29 requires use of a compound that binds a 5-HT5-receptor with at least 10 times greater binding affinity than the affinity for a 5-HT1D-receptor and must treat migraine in a subject. The Specification therefore must adequately describe that genus of compounds.

The written description requirement can be met by disclosing "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002).

The Specification states that 5-HT-5 receptor binding compounds may include "low molecular weight, usually synthetic compounds" (Specification 7). Binding compounds include 5-HT-5 specific antibodies, including polyclonal sera, monoclonal, chimeric and recombinant antibodies and antibody fragments (*see* Specification 7). The Specification also suggests the use of "aptamers, i.e. nucleic acids, as a rule oligonucleotides, having sufficient affinity for 5-HT5 receptors" (Specification 7). The Specification includes combinatorial substance libraries (*see* Specification 9).

The Specification also describes

> processes for the identification and characterization of binding partners according to the invention. These and further similarly suitable processes can form the basis for in vitro screening processes, with which it is possible to select from a large number of different compounds those which appear to be most promising with respect to future use.

(Specification 9.)

However, the Specification does not describe any structural features that are shared by compounds having the function of treating migraines using a "binding partner for a 5-HT5-receptor whose binding affinity for the 5-HT5-receptor is at least 10 times greater than its binding affinity for a 5-HT1D-receptor" (Claim 29). The Specification describes no specific binding partners which meet the claim requirements. Inconsistent with claim 29, the Specification comments "Binding partners which can be used for migraine treatment can bind to 5-HT5 with a lower, an essentially identical, or a higher affinity than to a specific receptor which is different from 5-HT5" (Specification 15).

The present case is therefore analogous to *Rochester*. In *Rochester*, the patent claimed a method of selectively inhibiting the enzyme PGHS-2 (also known as COX-2) by "administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human." *Rochester*, 358 F.3d at 918. The patent "describes in detail how to make cells that express either COX-1 or COX-2, but not both . . ., as well as assays for screening compounds, including peptides, polynucleotides, and small organic molecules to identify those that inhibit the expression or activity of the PGHS-2 gene product." *Rochester*, 358 F.3d at 927.

The court held that the disclosure of screening assays and general classes of compounds was not adequate to describe compounds having the desired activity: without disclosure of which peptides, polynucleotides, or small organic molecules have the desired characteristic, the claims were not adequately described. *See Rochester*, 358 F.3d at 927 ("As pointed out by

the district court, however, the '850 patent does not disclose just 'which "peptides, polynucleotides, and small organic molecules" have the desired characteristic of selectively inhibiting PGHS-2.' . . . Without such disclosure, the claimed methods cannot be said to have been described.").

Just as in *Rochester*, the present application discloses several genera of chemical compounds and assays for screening such compounds to identify those having the desired activity.

> As the district court pointed out: Tellingly, . . . what plaintiff's experts' [sic] do not say is that one of skill in the art would, from reading the patent, understand what compound or compounds-which, as the patent makes clear, are necessary to practice the claimed method-would be suitable, nor would one know how to find such a compound except through trial and error . . . . Plaintiff's experts opine that a person of ordinary skill in the art would understand from reading the '850 patent what method is claimed, but it is clear from reading the patent that one critical aspect of the method-a compound that selectively inhibits PGHS-2 activity-was hypothetical, for it is clear that the inventors had neither possession nor knowledge of such a compound.

*Rochester*, 358 F.3d at 925-26.

Just as in *Rochester*, it is hypothetical which compounds have the claimed activity of treating migraine and function as a binding partner for a 5-HT5-receptor whose binding affinity for the 5-HT5-receptor is at least 10 times greater than its binding affinity for a 5-HT1D-receptor. In the Specification, there is no possession or knowledge of any such specific compound.

Appellant argues that the "screening process is set forth in the present application and enables the skilled person to read out those compounds

which have the required binding affinity for a 5-HT5-receptor and selectivity over the 5-HT1D-receptor" (App. Br. 6). This argument conflates the issue of written description with that of enablement. These are separate statutory requirements. *See Rochester*, 358 F.3d at 921 ("an invention may be enabled even though it has not been described"). In this application, the enablement rejection was withdrawn by the Examiner (*see* Answer 3). Thus, the enablement arguments need not be addressed.

Appellant argues that the present situation differs from *Rochester* in not simply inhibiting activity but that "it is the relationship between the 5-HT5 binding affinity and the treatment of certain diseases which represents the contribution the present invention makes over the prior art" (App. Br. 7). We do not find this argument persuasive because in *Rochester*, a similar type of correlation between drug selectivity and treatment function was known. The inventors in *Rochester* had already "hypothesized that it would be possible to reduce inflammation without gastrointestinal side effects if a method could be found for selectively inhibiting the activity of COX-2 (i.e., inhibiting the activity of COX-2 without inhibiting COX-1 activity.)" *Rochester*, 358 F.3d at 918. This is virtually identical to the current fact pattern where treatment of the condition will operate by selectively binding with one receptor in favor of another (*see* Specification 15).

Appellant then relies upon the Garcia-Ladona Declaration to demonstrate that "one of ordinary skill in the art would be able to carry out the presently claimed invention" (App. Br. 7). Not only does the Declaration not address the description issue, but even the single compound

disclosed by the Declaration as functioning in the assay is not described in structural terms (*see* Garcia-Ladona Declaration 1-5). Even adding the disclosure of the Declaration to the Specification would not place the ordinary artisan in possession of HK02-01 itself because nothing other than the function of that compound is presented. No structural information whatsoever is presented. *See Regents of the Univ. of Cal. v. Eli Lilly*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) ("A description of what a material does, rather than of what it is, usually does not suffice.").

We affirm the rejection of claim 29 under 35 U.S.C. § 112, first paragraph, for lack of adequate written description. Claims 30-32 and 34-36 fall with claim 29.

CONCLUSION

In summary, we affirm the rejection of claim 29 under § 103(a). Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 30-32 and 34-36 under 35 U.S.C. § 103(a) as these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

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